EXAMINER'S AMENDMENT

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Susan Gorman on 18 November 2011.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 21 September was filed after the mailing date of the Non-final Office action mailed on 12 May 2011. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Note, however, some of the references have been crossed out, as they are already of record and/or have been previously considered by the Examiner.

Notice of Rejoinder

It is noted that the Restriction requirement set forth at p. 2 of the Office action mailed 17 December 2007 with respect to originally elected Group II (claims 10, 12, 15, 16 and 30-36) and Group III (claims 18-24, 37 and 38) is hereby withdrawn. Thus, claim(s) 18-24 (and new claims 37 and 38), originally withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention in the Office

Action of 28 March 2008, are hereby rejoined to claims 10, 12, 15, 16 and 30-36. In view of the above noted withdrawal of the Restriction requirement between Groups II and III, Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Amendment

Cancel claims 1-9 and 26-29.

Please amend the claims as follows:

In claims 12, 15, 16 and 30, replace "Claim 10" in line 1 with "claim 10."

Claim 18. A method for regenerating ~~the~~ periodontal tissue which comprises administering to a patient in need thereof an effective amount of the periodontal transplant of claim 10 to regenerate ~~the~~ periodontal tissue.

Claim 19. The method according to [c]laim 18 which regenerates ~~the~~ cementum.

Claim 20. The method according to [c]laim 18 which regenerates ~~the~~ periodontal ligament.

Claim 21. The method according to [c]laim 18 which regenerates ~~the~~ alveolar bone.

Claim 22. The method according to [c]laim 18 which ~~prevents the~~ reduces or inhibits apical invasion of gingival epithelium along ~~the~~ a dental root surface.

Claim 23. The method according to [c]laim 18 which regenerates ~~the~~ dental pulp.

Claim 24. The method according to claim 18, which enhances the production of repaired dentin in ~~the~~ a pulp cavity.

Claim 34. The periodontal transplant of claim 10, comprising ~~a~~ the neurotrophic factor and atelocollagen.

Claim 35. The periodontal transplant of claim 10, comprising ~~a~~ the neurotrophic factor and hyaluronic acid.

Claim 37. A method for regenerating ~~the~~ periodontal tissue which comprises administering to a patient in need thereof an effective amount of the periodontal transplant of claim 31 to regenerate ~~the~~ periodontal tissue.

Claim 38. The method according to claim 37, ~~wherein the~~which regenerates periodontal ligament ~~is regenerated~~.

Reasons for Allowance

The following is an Examiner's statement of reasons for allowance. Constantino et al. (of record) teach a biocompatible hydroxyapatite formulation that comprises hyaluronic acid and nerve growth factor (NGF—see p. 17, line 19 through p. 21, line 16 of Constantino et al.). Further, Constantino et al. describe how to make such a transplant, which would be useful in the periodontal guided tissue regeneration (p. 17, line 23 of Constantino et al). Preparation of the biocompatible hydroxyapatite is achieved by supplementing a liquid phase with "a crystal growth modifier, such as

hyaluronic acid." (p. 19, lines 11-13). The liquid phase is then augmented by the addition of the selected growth factor (see p. 20, line 6 of Constantino et al.) and NGF is contemplated at p. 18, line 18. Constantino et al. teach that the effective amount of growth factor is released in the range of 0.1 μg to 10 μg per cubic centimeter volume. Finally, Constantino teaches at p. 11 that their disclosed hydroxyapatite bioactive scaffold can be designed in such a way that the desired physical properties such as porosity, tensile and flexural strength, consistency, etc. can be exploited, as well as the resorption/biodegradation properties, thus demonstrating the high level of skill in the art with respect to designing hydroxyapatite crystals for periodontal implants. However, as noted above, Constantino et al. teach NGF and not brain derived neurotrophic factor (BDNF).

Although Tsuboi et al. (of record) teach that the neurotrophic factors BDNF, NGF and NT-3 all behave similarly in their effects upon mouse periodontal ligament cells (i.e., in vitro; see Figure 1B at p. 882; Figure 3D at p. 884 of Tsuboi et al.), the evidence presented in Exhibits 5 & 6 of the Remarks filed 21 September 2011 show that NGF does not regenerate the periodontal ligament or cementum in vivo, as required by the claims. Further, Exhibit 6 shows that NGF does not reduce or inhibit the apical invasion of gingival epithelium along the dental root surface as required by the claims. In addition, Mizuno et al. (J Periodontol., 2008; 79: 2182-2189—submitted on Applicant's 1449 form filed 21 September 2011) teach at p. 2188, that although the in vivo topical application of BDNF "resulted in the enhancement of periodontal tissue regeneration without ankylosis and epithelial cell downgrowth...the topical application of NGF...to

experimental periodontal tissue defects in beagle dogs did not enhance periodontal tissue regeneration." Thus, although it was known by Tsuboi et al., and others, at the time of filing that BDNF and NGF can behave similarly in vitro, the surprising or unexpected finding that BDNF further regenerates periodontal tissue in vivo, while NGF does not, could not have led one of ordinary skill in the art at the time of filing to the claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

These amendments are made to clarify the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 9:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Kolker can be reached on 571-272-3181. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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